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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,677	10/15/2003	Peter Rohdewald	103265-48964	7043

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EXAMINER	
STITZEL, DAVID PAUL	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/685,677	ROHDEWALD ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/12/03 & 12/13/0*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' election, with traverse, of the invention set forth in Group II encompassing claims 7-15, which was filed on November 4, 2005, in response to the restriction requirement as set forth in the Official Action dated October 7, 2005, is acknowledged.

Restriction/Election

Applicants' traversal of the aforementioned restriction requirement on the grounds that a prior art search and examination of the claims of the inventions set forth in Groups I and II would not be unduly burdensome is duly noted. However, a proper prima facie case of undue search burden associated with a prior art search and examination of the claims of the separate, distinct and independent inventions of Groups I and II has previously been established in the aforementioned Official Action. For example, as opposed to attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, a pharmaceutical composition comprising an arginine source (L-arginine), a proanthocyanidin (procyanidin) and a hormone (sterol), may alternatively be utilized in the treatment of hypertension and cardiovascular disease, as described in the Schmitz Pre-Grant Patent Application US2005/0164956 (abstract; [0080]; and [0097]). The alleged mischaracterization of the invention of Group II as being directed to a method of administering a pharmaceutical composition for "attaining enhanced sexual wellness" by stimulating stimulating nitric oxide synthase (NOS) activity, as opposed to a method of administering a pharmaceutical composition for the "treatment of erectile dysfunction" by stimulating nitric oxide synthase (NOS) activity, is duly noted. However, it does not appear as though the Applicants have set forth within the instant application an explanation or description as to what constitutes "attaining enhanced sexual wellness." Moreover, the only two

examples present within the instant application are both directed to treating erectile dysfunction by administering a pharmaceutical composition of the instant application. Assuming *arguendo* that the invention of Group II was in fact mischaracterized in the prior restriction requirement, said mischaracterization does not change the substance of the restriction requirement, since the pharmaceutical composition of Group I may alternatively be utilized in a method (i.e., treating hypertension and cardiovascular disease) that is materially different from the method claimed in the invention of Group II. As a result, the aforementioned restriction requirement is deemed proper and therefore made FINAL.

Status of Claims

Claims 1-16 are currently pending. Claims 1-6 and 16 are directed to the non-elected invention of Group I and are therefore withdrawn from consideration. Claims 7-15 are directed to the elected invention of Group II and are therefore examined herein on the merits for patentability.

Double Patenting

Statutory Double Patenting

A statutory double patenting rejection of the "same invention" type finds its support in the language of 35 U.S.C. § 101, which states in part that "whoever invents or discovers any new and useful process ... or composition of matter ... may obtain ***a*** patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 164 USPQ 619 (CCPA 1970). A statutory type (35 U.S.C. § 101) double patenting rejection can be overcome by either canceling or amending the conflicting claims so that they are no longer

coextensive in scope. However, the filing of a terminal disclaimer ***cannot*** overcome a double patenting rejection based upon 35 U.S.C. § 101.

Claims 7-11 and 12-15 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of conflicting claims 9-13 and 15-18, respectively, of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application). This is a provisional statutory double patenting rejection since the conflicting claims 9-13 and 15-18 have not yet in fact been patented but are of the same scope of claims 7-11 and 12-15 of the instant application.

Warning – Duplicate Claims

Applicant is advised that should claim 14 of the instant application be found allowable, claim 15 will be objected to under 37 CFR § 1.75 as being a substantial duplicate thereof. When ***two claims in an application*** are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Nonstatutory Double Patenting

A nonstatutory double patenting rejection of the "obviousness-type" is based on a judicially created doctrine grounded in public policy so as to prevent not only the unjustified or improper timewise extension of the "right to exclude" granted by a patent, but also possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re White*, 405 F.2d 904, 160 USPQ 417 (CCPA 1969); *In re*

Schneller, 397 F.2d 350, 158 USPQ 210 (CCPA 1968); and *In re Sarett*, 327 F.2d 1005, 140 USPQ 474 (CCPA 1964).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned or assigned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. See MPEP § 804. However, this does not mean that one is absolutely precluded from all use of the patent disclosure. See MPEP § 804. For example, the specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Furthermore, ***those portions of the specification which provide support for the patent claims may also be examined and considered*** when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-442, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* stated that one must first "determine how much of the patent disclosure pertains to the invention claimed in the patent" because only "[t]his portion of the specification supports the patent claims and may be considered." The court in *Vogel* also pointed out that "this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. § 103, since only the disclosure of the invention claimed in the patent may be examined."

1. Claims 7 and 12 of the instant application are rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claim 1 of U.S. Patent 6,565,851 (hereinafter the conflicting Rohdewald '851 patent).

More specifically, claims 7 and 12 of the instant application are directed to a method of administering a daily dosage of ingredients, or a pharmaceutical composition comprising said ingredients, for attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, wherein said ingredients of said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); and a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins).

Claim 1 of the conflicting Rohdewald '851 patent is directed to a method of relieving symptoms of erectile dysfunction by stimulating nitric oxide synthase (NOS) activity by administering a nitric oxide synthase substrate (e.g., L-arginine) and a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins). Relieving symptoms of erectile dysfunction is a species of the genus of attaining enhanced sexual wellness and as a result claim 1 of the conflicting Rohdewald '851 patent anticipates claims 7 and 12 of the instant application.

As a result, although claims 7 and 12 of the instant application are not identical to claim 1 of the conflicting Rohdewald '851 patent, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove.

2. Claims 7-15 of the instant application are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over conflicting claims 9-13 and

15-18 of copending U.S. Patent Application Serial Number 11/054,742 (hereinafter the conflicting Rohdewald '742 application).

More specifically, claims 7 and 12 of the instant application are directed to a method of administering a daily dosage of ingredients, or a pharmaceutical composition comprising said ingredients, for attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, wherein said ingredients of said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); and a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins). Claims 8 and 13 of the instant application are directed to a method of administering an elevated dosage of said pharmaceutical composition then lessened dosages thereafter while still providing enhanced sexual wellness. Claims 9-11 and 14-15 of the instant application are directed to a method of administering a daily dosage of ingredients, or a pharmaceutical composition comprising said ingredients, for attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, wherein said ingredients of said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins); and a hormone (e.g., sex hormone).

Claims 9 and 15 of the conflicting Rohdewald '742 application are directed to a method of administering a daily dosage of ingredients, or a pharmaceutical composition comprising said ingredients, for attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, wherein said ingredients of said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); and a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins). Claims 10 and 16 of the conflicting Rohdewald '742 application are directed to a method of administering an elevated dosage of said pharmaceutical composition then lessened dosages

thereafter while still providing enhanced sexual wellness. Claims 11-13 and 17-18 of the conflicting Rohdewald '742 application are directed to a method of administering a daily dosage of ingredients, or a pharmaceutical composition comprising said ingredients, for attaining enhanced sexual wellness by stimulating nitric oxide synthase (NOS) activity, wherein said ingredients of said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); a compound that stimulates nitric oxide synthesis (e.g., proanthocyanidins); and a hormone (e.g., sex hormone).

As a result, although claims 7-15 of the instant application are not identical to claims 9-13 and 15-18 of the conflicting Rohdewald '742 application, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope as discussed hereinabove. This is a provisional non-statutory double patenting rejection since the conflicting claims have not yet been patented.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102, which forms the basis of the anticipation rejections as set forth under this particular section of the Official Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-8 and 12-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by International Application Publication Number WO 00/00212 (hereinafter the Shell '212 publication).

With respect to claims 7 and 12 of the instant application, the Shell '212 publication discloses a method of administering a daily dosage (preferably from one-half hour to one hour prior to sexual activity) of active agents, administered either separately or together in the same pharmaceutical

composition, for treating erectile dysfunction and nitric oxide insufficiency, by stimulating nitric oxide synthase (NOS) activity, wherein said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., arginine); and a compound that enhances nitric oxide production (e.g., proanthocyanidins or Pycnogenol) (page 1, lines 15-17; page 2, lines 20-22; page 4, lines 9-11 and 16-19; page 5, lines 11-13; page 9, lines 1-12 and 19-21; page 10, lines 2 and 6-11; page 14, lines 7-27; page 15, lines 1-6; page 16, lines 12-30; page 17, lines 1-5 and 17-24). With respect to claims 8 and 13 of the instant application, the Shell '212 publication discloses a method of administering a higher optimum dosage level of said active agents then incrementally reducing the dosages thereof to a threshold dosage level sufficient to maintain an appreciable stimulation of nitric oxide synthase (NOS) activity (page 14, lines 7-18).

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11 and 14-15 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shell '212 publication in view of U.S. Patent 5,906,987 (hereinafter the Chwalisz '987 patent).

The teachings of the Shell '212 publication are incorporated herein by reference and are therefore applied in the instant rejection as discussed hereinabove.

With respect to claims 9-11 and 14-15 of the instant application, the Shell '212 publication teaches a method of administering a daily dosage (preferably from one-half hour to one hour prior to sexual activity) of active agents, administered either separately or together in the same pharmaceutical composition, for treating erectile dysfunction and nitric oxide insufficiency, by stimulating nitric oxide synthase (NOS) activity, wherein said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., arginine); and a compound that enhances nitric oxide production (e.g., proanthocyanidins or Pycnogenol) (page 1, lines 15-17; page 2, lines 20-22; page 4, lines 9-11 and 16-19; page 5, lines 11-13; page 9, lines 1-12 and 19-21; page 10, lines 2 and 6-11; page 14, lines 7-27; page 15, lines 1-6; page 16, lines 12-30; page 17, lines 1-5 and 17-24).

The Shell '212 publication does not explicitly teach additionally administering a hormone, as claimed in claims 9-11 and 14-15. However, the Chwalisz '987 patent teaches a method of administering a daily dosage of active agents, administered either sequentially or together in the same pharmaceutical composition, for treating impotence and nitric oxide insufficiency, by stimulating nitric oxide synthase (NOS) activity, wherein said pharmaceutical composition comprises: a nitric oxide synthase substrate (e.g., L-arginine); and/or a compound that stimulates nitric oxide synthesis; in combination with an androgen (e.g., testosterone) (column 4, lines 25-31, 51-54 and 60-67; column 8, lines 4-21; column 9, lines 20-25). The Chwalisz '987 patent also teaches a method of administering a higher dosage of said pharmaceutical composition then regulating downward the dosages thereof to a level sufficient to maintain relief from impotence (column 8, lines 4-21).

It would have been prima facie obvious to one of ordinary skill in the art at the time the instant application was filed to modify the method of the Shell '212 publication, which teaches a method of treating erectile dysfunction by administering a pharmaceutical composition comprising a nitric oxide

synthase substrate (e.g., arginine) and a compound that enhances nitric oxide production (e.g., proanthocyanidins or Pycnogenol), by further including within said pharmaceutical composition an androgen (e.g., testosterone), as taught by the Chwalisz '987 patent. One of ordinary skill in the art would have been motivated to incorporate an androgen (e.g., testosterone) into the pharmaceutical composition of the Shell '212 publication, so as to achieve additional desired affects for treating impotence, as reasonably suggested by the Chwalisz '987 patent.

Conclusion

Claims 7-15 are rejected because the claimed invention would have been anticipated and/or prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, is disclosed in and/or would have been reasonably suggested by the teachings of the cited prior art references.

Remarks

The following is a list of prior art patents and patent application publications made of record and considered pertinent to the applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

U.S. Pre-Grant Patent Application Publication 2002/0068365 (hereinafter the Kuhrts '365 publication);

D.E. Patent 19845314 (hereinafter the Rohdewald '314 patent); and

International Application Publication Number WO 99/45797 (hereinafter the Chevaux '797 publication).

Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, Esq. whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Sreenivasan Padmanabhan can be reached at 571-272-0629. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see http://pair-direct.uspto.gov. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David P. Stitzel, Esq.

MICHAEL HARTLEY
PRIMARY EXAMINER